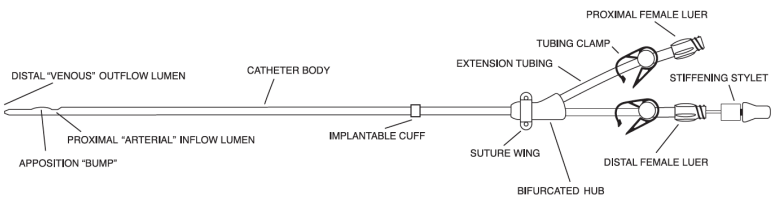
ProGuide™
chronic dialysis catheter

INSTRUCTIONS FOR USE

DESCRIPTION

The ProGuide Chronic Hemodialysis Catheter is made of soft radiopaque polyurethane called Carbothane®. It is available in 14.5 French size and a variety of lengths. The catheter shaft is divided internally into two separate lumens by a septum. It allows flow rates as high as 500 mL/min. The catheter has a white tissue ingrowth cuff to help anchor the catheter in position.



INDICATIONS FOR USE

The ProGuide Chronic Dialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis.

It may be implanted percutaneously and is primarily placed in the internal jugular or subclavian vein of an adult patient.

GENERAL CAUTION STATEMENTS

- Read instructions for use carefully before using device.
- RX ONLY - Federal Law (USA) restricts the device to sale by or on the order of a physician.
- Single Patient Use Only
- Sterilized by Ethylene Oxide (EO)
- Sterile and non-pyrogenic only if packaging is not opened, damaged or broken.
- Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by reuse of the catheter or accessories.
- Do not use the catheter or accessories if the packaging is open, damaged or compromised.
- Do not use the catheter or accessories if any sign of product damage is visible.

CONTRAINDICATIONS

- The ProGuide Chronic Dialysis Catheter is intended for long-term vascular access and should not be used for any purpose other than indicated in these instructions.

POTENTIAL COMPLICATIONS

The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications. Before attempting the insertion of the ProGuide catheter, the physician should be familiar with the following complications and their emergency treatment should they occur:

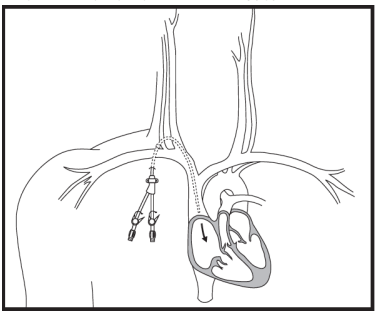
- Air embolism
- Bleeding at site
- Cardiac arrhythmia
- Catheter or cuff erosion through the skin
- Catheter occlusion
- Central venous thrombosis
- Catheter-related sepsis (septicemia)
- Exit site infection
- Extravasation
- Fibrin sheath formation
- Hemorrhage
- Hydrothorax
- Inflammation, necrosis or scarring of skin over implant area
- Laceration of vessels or viscus
- Mediastinal injury
- Pleural Injury
- Pulmonary emboli
- Right atrial puncture
- Subclavian artery puncture
- Thoracic duct injury (laceration)
- Thrombocytopenia
- Vascular (venous) thrombosis
- Vessel erosion
- Bacteremia
- Brachial plexus injury
- Cardiac tamponade
- Catheter embolism
- Catheter damage due to compression between the clavicle and first rib
- Endocarditis
- Exit site necrosis
- Exsanguination
- Hematoma
- Hemothorax
- Inferior vena cava puncture
- Intolerance reaction to implanted device
- Lumen thrombosis
- Perforation of vessels or viscus
- Pneumothorax
- Retroperitoneal bleeding
- Spontaneous catheter tip malposition or retraction
- Thromboembolism
- Tunnel infection
- Ventricular thrombosis
- Risks normally associated with local and general anesthesia, surgery, and post-operative recovery

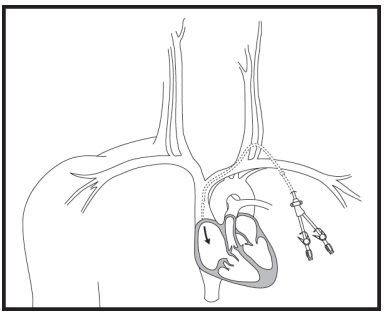
These and other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of hemodialysis catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

INSERTION SITES

The right internal jugular vein is a preferred anatomical location for chronic dialysis catheters. However, the left internal jugular vein, as well as the external jugular veins and subclavian veins can also be a consideration. As with all invasive procedures, the physician will assess the anatomical and physiological needs of the patient to determine the most appropriate catheter entry site. ProGuide is available in various lengths to accommodate the varying anatomical differences of patients as well as the differences between right and left side approaches. Catheters greater than 40 cm long are typically placed in the femoral vein.

PLACEMENT INTO RIGHT OR LEFT INTERNAL JUGULAR VEIN





WARNING: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation.
WARNING: Extended use of the subclavian vein may be associated with subclavian vein stenosis and thrombosis.
WARNING: The risk of infection is increased with femoral vein insertion.
WARNING: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

PREPARATION INSTRUCTIONS

1. Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
2. The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.
3. The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve correct tip placement, proper catheter length selection is important. Routine fluoroscopy should always follow the initial insertion of this catheter to confirm appropriate placement prior to use.

SITE PREPARATION

1. The patient should be placed in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the opposite side of the insertion site.
2. For internal jugular placement, have patient lift his/her head from the bed to define the sternomastoid muscle. The venous entry site will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle.
3. Prepare and maintain a sterile field throughout the procedure using standard institutional protocol for implantable devices.
   PRECAUTION: Follow Universal Precautions when inserting and maintaining this device. Due to the risk of exposure to bloodborne pathogens, health care professionals should always use standard blood and body fluid precautions in the care of all patients. Sterile technique should always be followed.
4. Prepare the sterile field and access site using an approved prep solution and standard Surgical technique.
   PRECAUTION: Use standard hospital protocols when applicable.
5. (If applicable) Administer local anesthesia to the insertion site and the path for the subcutaneous tunnel.

INSERTION TECHNIQUE (1) - COMMON STEPS
PERCUTANEOUS ENTRY INTO RIGHT INTERNAL JUGULAR VEIN
WITH A VALVED PEELAWAY SHEATH INTRODUCER

VENOUS ACCESS AND GUIDE WIRE INSERTION

1. K-DOQI Guidelines recommend the use of ultrasound guidance.
   NOTE: Mini access ("micropuncture") is recommended. Follow manufacturer's guidelines for proper insertion technique.
   Insert the introducer needle with an attached syringe and advance it into the target vein, in the direction of blood flow. Aspirate gently as the insertion is made. Aspirate a small amount of blood to ensure the needle is correctly positioned in the vein.
   PRECAUTION: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that the bleeding has stopped and that no hematoma has developed before attempting to cannulate the vein again.
2. When the vein has been entered, remove the syringe leaving the needle in place and place thumb over the hub of the needle to minimize blood loss and / or air embolism.
3. Insert the distal end of the marker guide wire into the needle hub (or mini access introducer hub) and pass it into the vasculature.
   PRECAUTION: If using the "J" tipped wire provided, draw the tip of the wire back into the straightener so that only the tip of the wire is exposed.
4. Advance the guide wire with forward motion until the tip resides at the junction of the superior vena cava and right atrium.
   WARNING: Cardiac arrhythmias may result if the guide wire is allowed to pass into the right atrium.
   CAUTION: Do not advance the guide wire or catheter if unusual resistance is encountered.
   CAUTION: Do not insert or withdraw the guide wire forcibly from any component. The wire may break or unravel. If the guide wire becomes damaged and must be removed while the needle (or sheath introducer) is inserted, the guide wire and needle should be removed together.
   PRECAUTION: The length of the guide wire inserted is determined by the size of the patient and the anatomical site used.
   PRECAUTION: Depth markings on the wire will help determine indwelling depth. Always confirm proper guide wire position using fluoroscopy.
5. Remove the needle (or mini access introducer), leaving the guide wire in place. The guide wire should be held securely during the procedure. The introducer needle must be removed first.

CATHETER PREPARATION AND SUBCUTANEOUS TRACT DILATION

1. Remove the stiffening stylet from the venous lumen.
   PRECAUTION: The ProGuide catheter is packaged with a guide wire stiffening stylet to facilitate placement using the over-the-wire technique and is not used with a peelaway introducer insertion technique (see insertion technique 2 for use of stiffener component).
2. Irrigate each lumen of the catheter with heparinized saline and clamp each extension prior to catheter insertion.
   WARNING: The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
   WARNING: To minimize the risk of air embolism, keep the catheter clamped at all times when not in use or when attached to a syringe, IV tubing, or bloodlines.
   WARNING: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation.
   CAUTION: Do not clamp the dual lumen portion of the catheter body. Clamp only the clear extension tubing.
   PRECAUTION: Only clamp the catheter with the in-line tubing clamps provided.
3. Determine the catheter exit site on the chest wall, approximately 8-10 cm below the clavicle that is below and parallel to the venous puncture site.
   PRECAUTION: A tunnel with a wide, gentle arc lessens the risk of catheter kinking. The distance of the tunnel should be short enough to keep the bifurcated junction from entering the exit site, yet long enough to keep the cuff 2-3 cm (minimum) from the skin opening site.
4. Make a small incision at the desired exit site of the tunneled catheter on the chest wall. The incision should be wide enough to accommodate the cuff, approximately 1 cm.
5. Use blunt dissection to create the subcutaneous tunnel opening at the catheter exit site for the white tissue ingrowth cuff, midway between the skin exit site and the venous entry site, approximately 2-3 cm (minimum) from the catheter exit site.
   WARNING: Do not over-expand the subcutaneous tissue during tunneling. Over-expansion may delay or prevent cuff in-growth.
6. Make a second incision above and parallel to the first, at the venous insertion site. Enlarge the cutaneous site with a scalpel and create a small pocket with blunt dissection to accommodate the small remaining catheter loop ("knuckle") of the catheter after the peel-away sheath is removed.
7. Attach the tunneler to the catheter's venous lumen. Slide the tip of the catheter over the tri-ball connection until it rests adjacent to the sheath stop.
8. Slide the tunneler sheath over the catheter making certain that the sleeve covers the arterial lumen. This will reduce the drag in the subcutaneous tunnel as the apparitional bump and arterial port pass through the tissue.
9. With the blunt tunneler, gently lead the catheter and tunneler connection into the exit site and create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site.
   CAUTION: The tunnel should be made with care to avoid damage to surrounding vessels. Avoid tunneling through muscle.
   CAUTION: Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. The catheter should not be forced through the tunnel.
10. After tunneling the catheter, the tunneler can be removed by sliding the tunneler sheath away from the catheter and pulling the tunneler from the distal tip of the catheter.
    CAUTION: Avoid damage to the catheter by using a slight twisting motion.
    CAUTION: To avoid damage to the catheter tip, keep the tunneler straight and do not pull it out at an angle.
    CAUTION: Inspect catheter tip for damage before proceeding with procedure

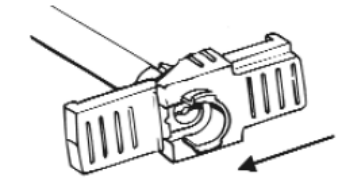
INTRODUCTION OF THE VALVED PEELAWAY INTRODUCER

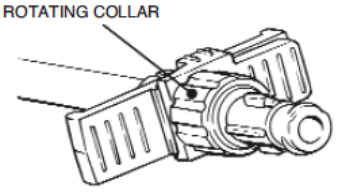
CAUTION: The sheath is not intended to create a complete two-way seal nor is it intended for arterial use.

CAUTION: The sheath is designed to reduce blood loss but it is not a hemostasis valve. The valve may substantially reduce the rate of blood flow but some blood loss through the valve may occur.

1. Insert the dilator through the valve and lock in place using the rotating collar.
   NOTE - Optional dilation:
   - To ease insertion of the peelaway introducer, some physicians prefer to dilate the vein before inserting the introducer.
   - Thread the dilator(s) over the end of the guide wire and advance into the vein using a rotating motion to assist passage through the tissue.

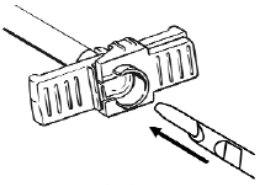
   CAUTION: As the dilator(s) pass through the tissue and into the vasculature, ensure that the guide wire does not advance further into the vein.
2. While maintaining guide wire position in the vein, advance the locked peelaway introducer and dilator assembly over the exposed guide wire and into the vein.
   WARNING: Never leave the sheath in place as an indwelling catheter. Damage to the vein will occur.
3. Hold the sheath in place and unlock the dilator assembly by turning the rotating collar. Gently withdraw the dilator and wire from the sheath leaving the valved introducer in place.
   NOTE: Leaving the guide wire in place after removing the dilator may cause the valve to leak.
   CAUTION: Care should be taken not to advance the split sheath too far into the vessel as a potential kink would create an impasse to the catheter.

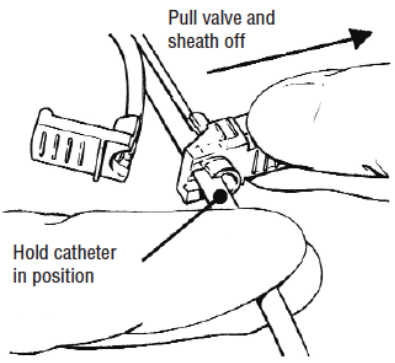




DIALYSIS CATHETER PLACEMENT

1. Advance the distal section of the catheter through the valved sheath introducer and into the vein.
   PRECAUTION: To help minimize catheter kinking, it may be necessary to advance in small steps by grasping the catheter close to the sheath.
2. Advance the catheter tip to the junction of the superior vena cava and right atrium.
3. With the catheter advanced and positioned, crack the sheath handle in half and peel partially away from the catheter.
   CAUTION: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and peel the sheath only a few centimeters at a time.
4. Near the valve, hold the catheter firmly in position and pull the valve off the catheter.
   PRECAUTION: It is normal to experience some resistance while pulling the catheter through the slit on the valve.
5. Remove the sheath completely from the patient and catheter.
6. Press the remaining catheter loop ("knuckle") gently into the subcutaneous pocket created at the venous entry site.
   WARNING: Catheters should be implanted carefully to avoid an sharp or acute angles which could compromise the flow of blo or occlude the opening of the catheter lumens.
   PRECAUTION: For optimal product performance do not insert a portion of the cuff into the vein.
7. Attach syringes to both extensions and open the clamps. Confirm correct placement and catheter function by aspirating blood from both lumens. Flush each lumen with heparinized saline (priming volume is printed on the extension tubing clamp). Blood should aspirate easily.
   PRECAUTION: If either lumen exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flow.
   PRECAUTION: It is recommended that the "venous" luer connec tion be oriented cephalad (toward the head).
8. Clamp the extensions immediately after flushing.
9. Remove the syringes and replace with injection caps.
   PRECAUTION: Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter prior to each use. Always aspirate first then irrigate the catheter prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
10. Correctly position the cuff and tunneled portion of the catheter.
11. Confirm proper tip placement with fluoroscopy. The distal "venous" tip should be positioned at the junction of the superior vena cava and right atrium or into the right atrium for optimal blood flow.
    WARNING: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.
12. Secure and dress the catheter as noted in "Securement and Dressing"





INSERTION TECHNIQUE (2) - COMMON STEPS
PERCUTANEOUS ENTRY INTO RIGHT INTERNAL JUGULAR VEIN
WITH AN OVER-THE-WIRE TECHNIQUE

VENOUS ACCESS AND GUIDE WIRE INSERTION

1. K-DOQI Guidelines recommend the use of ultrasound guidance.
   NOTE: Mini access ("micropuncture") is recommended. Follow manufacturers guidelines for proper insertion technique.
   Insert the introducer needle with an attached syringe and advance it into the target vein, in the direction of blood flow. Aspirate gently as the insertion is made. Aspirate a small amount of blood to ensure the needle is correctly positioned in the vein.
   PRECAUTION: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that the bleeding has stopped and that no hematoma has developed before attempting to cannulate the vein again.
2. When the vein has been entered, remove the syringe leaving the needle in place and place thumb over the hub of the needle to minimize blood loss and / or air embolism.

3. Insert the distal end of the marker guide wire into the needle hub (or mini access introducer hub) and pass it into the vasculature.
   PRECAUTION: If using the "J" tipped wire provided, draw the tip of the wire back into the straightener so that only the tip of the wire is exposed.
4. Advance the guide wire with forward motion until the tip resides in the junction of the superior vena cava and right atrium.
   WARNING: Cardiac arrhythmias may result if the guide wire is allowed to pass into the right atrium.
   CAUTION: Do not advance the guide wire or catheter if unusual resistance is encountered.
   CAUTION: Do not insert or withdraw the guide wire forcibly from any component. The wire may break or unravel. If the guide wire becomes damaged and must be removed while the needle (or sheath introducer) is inserted, the guide wire and needle should be removed together.
   PRECAUTION: The length of the guide wire inserted is determined by the size of the patient and the anatomical site used.
   PRECAUTION: Always confirm proper guide wire position using fluoroscopy. Depth markings on the wire will help determine indwelling depth.
5. Remove the needle (or mini access introducer), leaving the guide wire in place. The guide wire should be held securely during the procedure. The introducer needle must be removed first.

CATHETER PREPARATION AND SUBCUTANEOUS TRACT DILATION

1. The ProGuide catheter is packaged with a guide wire stiffening stylet positioned in the venous lumen to facilitate placement using the over-the-wire technique.
2. Withdraw the stiffening stylet approximately 2-3 cm and confirm that the stylet tip is not visible at the end of the catheter.
3. Irrigate the arterial lumen and stiffening stylet with heparinized saline and clamp the red arterial extension prior to catheter insertion.
   WARNING: The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
   WARNING: To minimize the risk of air embolism, keep the catheter clamped at all times when not in use or when attached to a syringe, IV tubing, or bloodlines.
   WARNING: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation.
   CAUTION: Do not clamp the dual lumen portion of the catheter body. Clamp only the clear extension tubing.
   PRECAUTION: Only clamp the catheter with the in-line tubing clamps provided.
4. Determine the catheter exit site on the chest wall, approximately 8-10 cm below the clavicle that is below and parallel to the venous puncture site.
   PRECAUTION: A tunnel with a wide, gentle arc lessens the risk of catheter kinking. The distance of the tunnel should be short enough to keep the bifurcated junction from entering the exit site, yet long enough to keep the cuff 2-3 cm (minimum) from the skin opening site.
5. Make a small incision at the desired exit site of the tunneled catheter on the chest wall. The incision should be wide enough to accommodate the cuff, approximately 1 cm.
6. Use blunt dissection to create the subcutaneous tunnel opening at the catheter exit site for the white tissue ingrowth cuff, midway between the skin exit site and the venous entry site, approximately 2-3 cm minimum from the catheter exit site.
   WARNING: Do not over-expand the subcutaneous tissue during tunneling. Over-expansion may delay or prevent cuff in-growth.
7. Make a second incision above and parallel to the first, at the venous insertion site. Enlarge the cutaneous site with a scalpel and create a small pocket with blunt dissection to accommodate the small remaining catheter loop ("knuckle") of the catheter.
8. Attach the tunneler to the catheter's venous lumen. Slide the tip of the catheter over the tri-ball connection until it rests adjacent to the sheath stop.
9. Slide the tunneler sheath over the catheter making certain that the sleeve covers the arterial lumen. This will reduce the drag in the subcutaneous tunnel as the apposition bump and arterial port pass through the tissue.
10. With the blunt tunneler, gently lead the catheter and tunneler connection into the exit site and create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site.
    CAUTION: The tunnel should be made with care to avoid damage to surrounding vessels. Avoid tunneling through muscle.
    CAUTION: Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. The catheter should not be forced through the tunnel.
11. After tunneling the catheter, the tunneler can be removed by sliding the tunneler sheath away from the catheter and pulling the tunneler from the distal tip of the catheter.
    CAUTION: Avoid damage to the catheter by using a slight twisting motion.
    CAUTION: To avoid damage to the catheter tip, keep the tunneler straight and do not pull it out at an angle.
    CAUTION: Inspect catheter tip for damage before proceeding with procedure.
12. Remove the stylet label and tighten down the luer lock nut of the stylet to the blue venous luer lock connection.
13. Thread the distal tip of the stylet with the catheter over the proximal tip of the guide wire until the guide wire exits the venous luer connection.
14. While maintaining guide wire position in the vein, advance catheter to the junction of the superior vena cava and right atrium to ensure optimal blood flow.
    PRECAUTION: To help minimize catheter kinking, it may be necessary to advance in small steps by grasping the catheter close to the skin.
15. Remove the stylet and guide wire from the venous lumen.
16. Press the small remaining catheter loop ("knuckle") gently into the subcutaneous pocket created at the venous entry site.
    WARNING: Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the flow of blood or occlude the opening of the catheter lumens.
    PRECAUTION: For optimal product performance do not insert any portion of the cuff into the vein.
17. Make any adjustments to the catheter insertion depth and tip position under fluoroscopy.
18. Attach syringes to both extensions and open the clamps. Confirm correct placement and catheter function by aspirating blood from both lumens. Flush each lumen with heparinized saline (priming volume is printed on the extension tubing clamp). Blood should aspirate easily.
    PRECAUTION: If either lumen exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flow.
    PRECAUTION: To maintain patency, a heparin lock must be created in both lumens.
    PRECAUTION: It is recommended that the "venous" lumen be oriented cephalad (toward the head).
19. Clamp the extensions immediately after flushing.
20. Remove the syringes and replace with injection caps.
    CAUTION: Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter prior to each use.
21. Correctly position the cuff and tunneled portion of the catheter.
22. Confirm proper tip placement with fluoroscopy. The distal "venous" tip should be positioned at the junction of the superior vena cava and right atrium or into the right atrium for optimal blood flow.
    WARNING: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

SECUREMENT AND DRESSING

1. Suture the pocket created for the small remaining catheter loop ("knuckle") at the venous entry site.
2. If necessary, suture the catheter exit site.
3. Suture the catheter to the skin with the suture wing.
   WARNING: Do not suture through any part of the catheter. If sutures are used to secure the catheter, make sure they do not occlude or cut the catheter. Catheter tubing may tear when subjected to excessive force or rough edges.
   PRECAUTION: The catheter must be secured / sutured for the entire duration of implantation.
4. Apply transparent site dressing to catheter exit site and the tunneled insertion site using standard institutional protocol.
   WARNING: Do not use sharp instruments near the extension tubing or catheter body.
   WARNING: Do not use scissors to remove dressing.
   WARNING: Alcohol or alcohol-containing antiseptics may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact with the solution(s).
   WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters.
5. Record the catheter length and catheter lot number on the patient's chart. Note in the chart that Acetone and PEG-containing ointments should not be used with this device.

SITE CARE

1. Clean the skin around the catheter.
   WARNING: Use of ointments/creams at the wound site is not recommended.
2. Cover the exit site with occlusive dressing and leave extensions, clamps, and caps exposed for access by dialysis team.
3. Wound dressings must be kept clean and dry.
   CAUTION: Patients must not swim or soak the dressing unless instructed by a physician.
   PRECAUTION: If profuse perspiration or accidental wetting compromises adhesion of the dressing, the medical and nursing staff must change the dressing under sterile conditions.

CATHETER REMOVAL

As with all invasive procedures, the physician will assess the anatomical and physiological needs of the patient to determine the most appropriate catheter removal technique. The white implantable retention cuff facilitates tissue ingrowth, therefore the catheter must be surgically removed.

WARNING - Only a physician familiar with the appropriate removal techniques should attempt to remove an implanted chronic dialysis catheter.

CAUTION: Always review institutional protocol, potential complications and their treatment, warnings and precautions prior to catheter removal.

CAUTION STATEMENTS REGARDING HEMODIALYSIS TREATMENT

- Hemodialysis should be performed under a physician's instruction using approved institutional protocol.
- The heparin solution must be removed from each lumen prior to treatment to avoid systemic heparinization of the patient. Aspiration should be based on institutional protocol.
- Before dialysis begins, all connections to the catheter and extracorporeal circuits should be examined carefully.
- Accessories and components used in conjunction with this catheter should incorporate luer-lock adapters.
- Frequent visual inspection should be conducted to detect leaks and to minimize blood loss or air embolism.
- Repeated over-tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure.
- If a leak in the catheter tubing or hub occurs, or if a connector separates from any component during insertion or use, clamp the catheter and take all necessary steps and precautions to prevent blood loss or air embolism.
- To minimize the risk of air embolism, keep the catheter clamped at all times when not attached to a syringe, IV tubing, or bloodlines.
- Close all clamps in the center of the extension tubing. Repeated clamping near or on the luer lock connectors may cause tubing fatigue and possible disconnection.
- Clamping of the tubing repeatedly in the same location may weaken the tubing. Extension tubing may develop cuts or tears if subjected to excessive pulling or contact with rough edges.

POST DIALYSIS HEPARINIZATION

Follow institutional protocol for heparin concentration. If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.

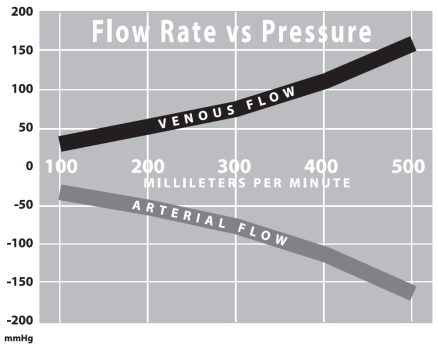
1. Draw the heparin / saline solution into two syringes, corresponding to the amount designated on the arterial and venous extension tubing clamp. Assure that the syringes are free of air.
2. Attach a syringe containing heparin solution.
3. Open the extension tubing clamp.
4. Aspirate to ensure that no air will be forced into the patient.
5. Inject the heparin solution into each lumen using a quick bolus technique.
   PRECAUTION: To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.
6. Close extension clamps.
   PRECAUTION: Extension clamps should only be open for aspiration, flushing, and dialysis treatment.
7. Remove syringes.
   PRECAUTION: In most instances, no further heparin flush will be necessary for 48-72 hours, provided the lumens have not been aspirated or flushed.
8. Assure luers are capped.

CATHETER PERFORMANCE PRIMING VOLUMES

- The priming volumes of both the arterial and venous lumens are printed on each extension tubing clamp.

FLOW RATE

- Typical flow rate vs. pressure with the ProGuide 14.5 FR X 28 cm (tip to hub) catheter (with side holes)



TROUBLESHOOTING INSUFFICIENT FLOWS

Treatment for insufficient flow will be at the discretion of the physician. Excessive force should not be used to flush an obstructed lumen. Insufficient blood flow may be caused by an occluded lumen due to clotting or fibrin sheath or because the arterial hole is contacting the vein wall. If manipulation of the catheter or reversing arterial and venous lines does not help, the physician may attempt to dissolve the clot with a thrombolytic agent.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This condition is usually caused by tip malposition. One of the following adjustments may resolve the obstruction:

- Reposition the catheter
- Reposition the patient
- Have the patient cough
- Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.

INFECTION

Catheter related infection is a serious concern of indwelling catheters. Follow institutional protocol when removing the catheter.

MERITMEDICAL®

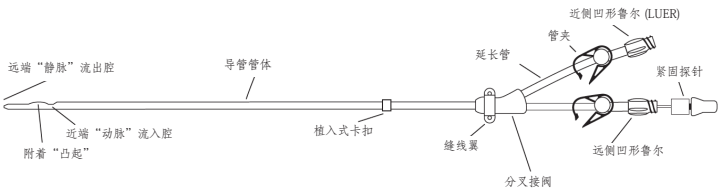
www.merit.com

Manufacturer:
Merit Medical Systems, Inc. South Jordan, Utah 84095 • U.S.A. 1-801-253-1600
U.S.A. Customer Service 1-800-356-3748

ProGuide™
血液透析用导管及附件

使用说明

产品描述
ProGuide 慢性血液透析导管由称为 Carbothane® 的软质射线不透性聚氨酯制成。该导管具有 14.5 法国尺寸以及各种长度。导管轴被一个隔膜分为两个独立的管腔。它允许的流速可高达 500 mL/min。导管有一个促进组织向内生长的白色卡扣，有助于固定导管到位。



适用范围
该产品用于血液透析和净化的长期血管介入。可经皮植入并且安置于成年患者颈部或锁骨下静脉中。

一般警示声明
- 使用装置前请仔细阅读使用说明。
- 仅凭处方销售 — 联邦法律（美国）限定本装置仅可由医师或凭医师处方销售。
- 仅可用于一名患者
- 使用环氧乙烷 (EO) 灭菌
- 仅在包装未打开、损坏或破损的情况下为无菌、无热原产品。
- 请勿采用任何方法对导管或组件重新灭菌。制造商不会为重复使用导管或附件所致的任何损害负责。
- 如果产品包装已打开、破损或泄漏，请勿使用导管或附件。
- 如果发现产品有任何受损迹象，请勿使用导管或附件。

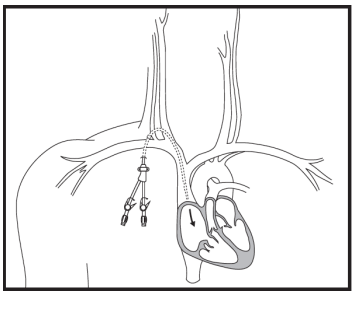
禁忌症
- ProGuide 慢性透析导管旨在用作长期血管通路，不应用于本说明指示之外的任何其它目的。

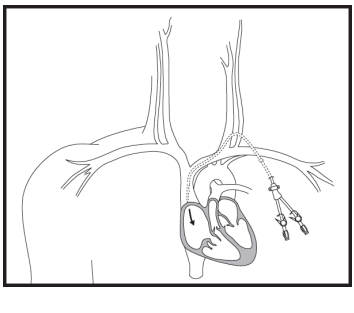
潜在并发症
留置中心静脉导管的使用为重症患者提供了一个重要的静脉通道；然而也存在出现严重并发症的可能性。尝试插入 ProGuide 导管之前，医师应熟悉以下并发症，以及出现此类并发症时的急救措施：
- 气栓
- 创口出血
- 心律失常
- 导管或卡扣侵蚀皮肤
- 导管闭塞
- 中心静脉血栓形成
- 与导管相关的败血症（败血病）
- 出口部位感染
- 溢血
- 血纤维蛋白外鞘形成
- 出血
- 胸腔积液
- 植入区域皮肤炎症、坏死或瘢痕
- 血管或内脏撕裂
- 纵隔损伤
- 胸膜损伤
- 肺栓塞
- 右心房穿孔
- 锁骨下动脉穿孔
- 胸导管损伤（撕裂）
- 血小板减少
- 血管（静脉）血栓形成
- 血管糜烂
- 菌血症
- 臂丛损伤
- 心包填塞
- 导管栓塞
- 锁骨与第一肋骨之间挤压所致的导管损坏
- 心内膜炎
- 出口部位组织坏死
- 严重失血
- 血肿
- 血胸
- 下腔静脉穿孔
- 对植入装置的排斥反应
- 管腔血栓形成
- 血管或内脏穿孔
- 气胸
- 腹膜后出血
- 导管顶端自发性错位或回缩
- 血栓栓塞
- 通道感染
- 心室血栓形成
- 与局部及全身麻醉、手术和术后恢复相关的常见风险

上述及其他并发症在医学文献中有详细记载，在置入导管之前应仔细考虑这些并发症的可能性。血液透析导管的置入和维护应由知晓该操作程序中所涉风险且有资格执行该程序的人员进行。

插入部位
右颈内静脉是放置慢性透析导管的较好解剖位置。但也可以考虑左颈内静脉以及颈外静脉和锁骨下静脉。与所有有创手术一样，医师将评估患者的解剖学和生理学需要，以确定最合适的导管入口部位。ProGuide 具有各种长度，以适应患者的各种解剖差异以及左侧与右侧方法之间的差异。40 cm 以上的导管通常置入股静脉内。

置入右颈内静脉或左颈内静脉





警告：对于需要呼吸机支持的患者，在锁骨下静脉置入时发生气胸的风险将增加。
警告：延长使用锁骨下静脉可能涉及锁骨下静脉狭窄及血栓形成。
警告：股静脉插管会增加感染的风险。
警告：如未能使用 X 线透视确认导管的放置，可能会导致严重创伤或致命并发症。

准备说明
1. 使用此装置前，请认真阅读说明。导管应由合格执业医师或由其他合格医护专业人员在医师指导下插入、控制及取出。
2. 这些使用说明中所描述的医疗技术以及操作程序并不完全代表所有医学可接受的方案，在治疗具体患者时也不能代替医师的经验和判断。
3. 由医师全权酌情选择适当的导管长度。为使顶端放置正确，选择适当的导管长度十分重要。初期插入导管后，务必进行常规 X 线透视，以确定在使用前放置是否得当。

部位准备
1. 应让患者处于调整后的垂头仰卧位，露出胸部上部，头略微偏向与插入部位相对的一侧。
2. 颈内放置时，让患者从床上抬起头以确定胸锁乳突肌。静脉入口部位将会选在两块胸锁乳突肌顶部之间形成的三角区顶点位置。该顶点应在锁骨上方约三指宽处。
3. 在整个手术过程中按照标准机构规程为植入式装置准备及维持一个无菌区。
   注意事项：插入和维护此装置时，请遵守通用注意事项。由于存在血源性病原体暴露风险，医护专业人员在护理所有患者时应始终遵守标准的血液和体液注意事项。还需一直采用无菌技术。
4. 采用获批准的准备溶液和标准外科技术准备无菌区和刺入部位。
   注意事项：适当时采用标准医院规程。
5. （如适用）对插入部位和皮下通道的通路实施局部麻醉。

插入技术 (1) — 常见步骤
配合使用带阀的剥式导管鞘经皮进入右侧颈内静脉

静脉进入及导丝插入
1. K-DOQI 指南推荐使用超声引导。
   注意：推荐采用微小穿刺（“微刺”）。参照制造商指南上的正确插入技术。
   插入带有注射器的导引针并顺着血流方向将其推入目标血管。插入后轻轻抽吸。抽出少量血液，以确保针正确位于静脉中。
   注意事项：如果动脉血被抽出，拔出针并立即按压针刺部位至少 15 分钟。确保出血已停止且未出现血肿，方可尝试将导管再次插入静脉。
2. 插入静脉后，取走注射器并将穿刺针留在原位，将大拇指放在针的接阀上以减少失血及／或气栓。
3. 将标记导丝的远端插入穿刺针接阀（或迷你插管器接阀）并将其推入脉管系统。
   注意事项：如使用厂家提供的 “J” 型头导丝，将导丝的顶端拉回拉直器，只让导丝的末端外露。
4. 向前拉动导丝，直至末端位于上腔静脉和右心房的交汇处。
   警告：若允许导丝进入右心房，可能会导致心律不齐。
   警示：遇到异常阻力时切勿强推导丝或导管。
   警示：切勿在任何组件中用力插入或抽回导丝。导丝可能会断裂或拆散。如果导丝因损坏而必须取出，而穿刺针（或导管鞘）已插入，则应将导丝和穿刺针一同取出。
   注意事项：插入导丝的长度取决于患者的体型大小及施用的身体部位。
   注意事项：可借助导丝上的深度标记确定留置深度。应始终使用 X 线透视来确认导丝位置得当。
5. 取出穿刺针（或迷你导管鞘），将导丝留在原位。在此程序中，应保持导丝的稳固。应首先移除导引针。

导管的准备和皮下脉管扩张
1. 将加硬管芯从静脉腔中移除。
   注意事项：ProGuide 导管配有一根便于导管安放的导丝加硬管芯，它采用沿导线推送 (over-the-wire) 技术，而不是剥式导管鞘插入技术（加硬管芯组件的用法请见插入技术 2）。
2. 用肝素化生理盐水灌洗导管的每个管腔，插入导管前先夹住各延长管。
   警告：在使用导管前，为避免患者全身肝素化，必须将两个管腔中的肝素溶液吸出。
   警告：为尽可能降低引发气栓的风险，导管在未使用或与注射器、静脉输液管路或血路管连接时，应始终用管夹夹紧。
   警告：对于需要呼吸机支持的患者，在锁骨下静脉置入时发生气胸的风险将增加。
   警示：不要夹住导管管体的双腔部位，只可夹住透明的延长管。
   注意事项：只能用厂家提供的直插式管夹来夹住导管。
3. 确定胸壁上的导管出口部位，在锁骨下方约 8-10 cm 处，即静脉穿刺部位下方的平行处。
   注意事项：带有平缓宽弧的通道可降低导管扭结的风险。通道的距离不宜太长，以免双分叉交汇处进入出口部位；但也不宜太短，以确保卡扣距离皮肤切口部位（至少）2-3 cm。
4. 在胸壁的通道导管的所需出口部位上做一个小切口。切口的宽度应足够容纳卡扣，约为 1 cm。
5. 在导管出口部位使用钝性分离，从而为促进组织向内生长的白色卡扣开设一个皮下通道开口，该开口应位于皮肤出口部位与静脉刺入部位的中间，距离导管出口部位（至少）约 2-3 cm。
   警告：在开设通道时切勿过度扩张皮下组织。过度扩张皮下组织可能会延迟或阻止卡扣向内生长。
6. 在静脉插入部位，在第一个切口的上方平行做出第二个切口。用手术刀扩大皮肤切口，再用钝性分离造出一个小袋状切口，以在移除剥式导管鞘之后容纳导管的小段余留导管环（“弯曲导管”）。
7. 将脉管推进器推进器与导管静脉腔相连接。将导管顶端滑动到三珠接头上，直到停在止动鞘处为止。
8. 将推进器推进器鞘沿着导管滑动，确保套管覆盖住动脉腔。这将减轻附着凸起和动脉接口通过组织时对皮下通道的拉扯。
9. 使用钝性推进器推进器轻轻地将导管与推进推进器连接引入至出口部位，并从导管出口部位处造出一个皮下通道，在静脉入口部位显露出来。
   警示：造通道时应小心，以免损伤周围血管。避免通道穿过肌肉。
   警示：切勿拉扯或拖拽导管管道。如遇到阻力，进一步钝性分离可能便于插入。不得强推导管以通过通道。
10. 在造好导管通道后，将推进器推进器鞘滑出导管并从导管远端部分的顶端拉出，即可移除推进器推进器。
    警示：采用轻微扭转手法，以免损坏导管。
    警示：为避免损坏导管顶端，应始终保持推进器推进器笔直，切勿倾斜拉出。
    警示：在手术前检查导管顶端有无损坏

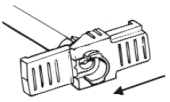
带阀剥式导管鞘的引入

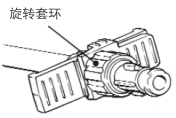
警示：鞘并非用于造出完全双向密封，也并非用于动脉。

警示：鞘旨在减少失血，但它并非止血阀。阀门可大幅降低血液流速，但也可能出现血液经由阀门流失。

1. 将扩张器穿过阀门，并用旋转套环固定。
   注意 — 选择性扩张：
   - 为便于插入剥式导管鞘，某些医师偏向于在插入导管鞘之前扩张血管。
   - 将扩张器绕在导丝末端并旋转着（目的是帮助扩张器穿过组织）将其推进血管内。

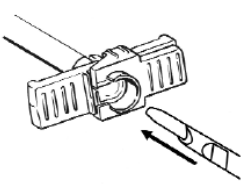
   警示：扩张器穿过组织进入脉管系统时，确保导丝不再向血管深处推进。
2. 保持导丝在血管内的位置固定，将锁定的剥式导管鞘和扩张器组件推到外露的导丝上并推入血管中。
   警告：切勿将鞘留在原位作为留置导管，这会损伤静脉。
3. 使鞘保留在原位并转动旋转套环以解开扩张器组件。从鞘中轻轻抽出扩张器和导丝，使带阀导管鞘留在原位。
   注意：移除扩张器后将导丝留在原位可能会引起阀门泄漏。
   警示：应格外小心，不要将分裂鞘推入血管过深，因为可能出现的扭结会导致导管被卡住。

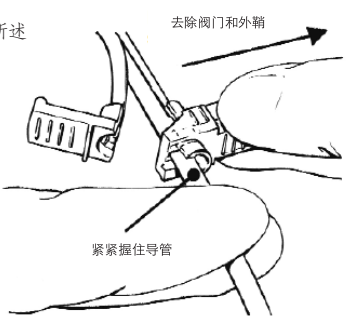




透析导管的放置

1. 将导管的远端部分推过带阀导管鞘并推入血管中。
   注意事项：为减少导管扭结，可能需要握住贴近鞘的导管小幅度推进。
2. 将导丝的末端推进到上腔静脉和右心房的交汇处。
3. 导管推进并定位后，将鞘柄分为两半并将其部分与导管分离。
   警示：切勿撕扯仍留在血管内的外鞘。为避免血管损伤，尽量将鞘往回拉，且一次只将鞘分开几厘米。
4. 在阀门附近，紧紧握住导管并将阀门从导管上拉脱。
   注意事项：从阀门的孔隙中拉出导管时遇到一些阻力是正常现象。
5. 将鞘完全从患者以及导管上拆下。
6. 将留置的导管环（“弯曲导管”）轻轻压入静脉刺入部位造出的皮下囊袋。
   警告：植入导管时应小心避免任何锋角或尖角，因为这可能会影响血液流动或堵塞导管管腔的开口。
   注意事项：为使本产品发挥最佳性能，请勿将卡扣的任何部分插入静脉中。
7. 将注射器同时与两个延长管连接，然后打开管夹。从双腔中抽吸血液，以确认放置是否正确，以及导管是否正常运作。用肝素化生理盐水（延长管管夹上标有预充量）冲洗各管腔。血液应被轻易吸入。
   注意事项：若任一管腔在抽吸血液时过度受阻，则可能需要旋转或重新定位导管，以获得足够的血流量。
   注意事项：建议“静脉”鲁尔接头朝向头侧（对着头部）。
8. 冲洗完毕后立即夹上延长管。
9. 移除注射器并更换为注射帽。
   注意事项：为避免发生气栓，应确保延长管在未被使用时始终用管夹夹紧，并在每次使用前抽吸并冲洗导管。每次使用前，应始终先抽吸再冲洗导管。每次对导管的连接进行改动时，应清除导管和所有连接管以及保护帽内的空气。
10. 正确放置导管的卡扣及通道部分。
11. 使用 X 线透视确认末端位置得当。远端的“静脉”末端应位于上腔静脉和右心房的交汇处，或置入右心房，以获得最佳的血流量。
    警告：如未能使用 X 线透视确认导管的放置，可能会导致严重创伤或致命并发症。
12. 导管固定及包扎，如“固定及包扎”部分所述





插入技术 (2) — 常见步骤
采用沿导线推送技术

进行经皮右颈内静脉的插入

静脉进入及导丝插入

1. K-DOQI 指南推荐使用超声引导。
   注意：推荐采用微小穿刺（“微刺”）。参照制造商指南上的正确插入技术。
   插入带有注射器的导引针并顺着血流方向将其推入目标血管。插入后轻轻抽吸。抽出少量血液，以确保针正确位于静脉中。
   注意事项：如果动脉血被抽出，拔出针并立即按压针刺部位至少 15 分钟。确保出血已停止且未出现血肿，方可尝试将导管再次插入静脉。
2. 插入静脉后，取走注射器并将针头留在原位，将大拇指放在针头的接阀上以减少失血及／或气栓。
3. 将标记导丝的远端插入针头接阀（或迷你插管器接阀）并将其推入脉管系统。
   注意事项：如使用厂家提供的 “J” 型头导丝，将导丝的顶端拉回拉直器，只让导丝的末端外露。
4. 向前拉动导丝，直至末端位于上腔静脉和右心房的交汇处。
   警告：若允许导丝进入右心房，可能会导致心律不齐。
   警示：遇到异常阻力时切勿强推导丝或导管。

警示：切勿在任何组件中用力插入或抽回导丝。导丝可能会断裂或解开。如果导丝因损坏而必须拆除，而针头（或导管鞘）已插入，则应将导丝和针头一同拆除。
注意事项：插入导丝的长度取决于患者的体型大小及施用的身体部位。
注意事项：应始终使用 X 线透视来确认导丝位置得当。可借助导丝上的深度标记确定留置深度。
5. 移除针头（或迷你插管器），将导丝留在原位。在此程序中，应保持导丝的稳固。应首先移除导引针。

导管的准备和皮下道扩张
1. ProGuide 导管配有一根置于静脉腔中的导丝加硬管芯，它采用沿导线推送 (over-the-wire) 技术，便于导管的安放。
2. 抽回加硬件管芯约 2-3 cm，然后确认导管末端的管芯末端是否已不可见。
3. 用肝素化生理盐水灌洗动脉腔和加硬管芯，接着夹住红色的动脉延长管，然后再插入导管。
警告：在使用导管前，为避免患者全身肝素化，必须将两个管腔中的肝素溶液吸出。
警告：为尽可能降低引发气栓的风险，导管在未使用或与注射器、静脉输液管路或血路管连接时，应始终用管夹夹紧。
警告：对于需要呼吸机支持的患者，在锁骨下静脉置入时发生气胸的风险将增加。
警示：不要夹住导管管体的双腔部位，只可夹住透明的延长管。
注意事项：只能用厂家提供的直插式管夹来夹住导管。
4. 确定胸壁上的导管出口部位，在锁骨下方约 8-10 cm 处，即静脉穿刺部位下方的平行处。
注意事项：带有平缓宽弧的通道可降低导管扭结的风险。通道的距离不宜太长，以免双分叉交汇处进入出口部位；但也不宜太短，以确保卡扣距离皮肤开口部位（至少）2-3 cm。
5. 在胸壁的通道导管的所需出口部位上做一个小切口。切口的宽度应足够容纳卡扣，约为 1 cm。
6. 在导管出口部位使用钝性分离，从而为促进组织向内生长的白色卡扣开设一个皮下通道开口，该开口应位于皮肤出口部位与静脉刺入部位的中间，距离导管出口部位至少约 2-3 cm。
警告：在开设通道时切勿过度扩张皮下组织。过度扩张皮下组织可能会延迟或阻止卡扣向内生长。
7. 在静脉插入部位，在第一个切口的上方平行做出第二个切口。用手术刀扩大皮肤切口，再用钝性分离造出一个袋状切口，以容纳导管的小段余留导管环（“弯曲导管”）。
8. 将推进器与导管静脉腔相连接。将导管顶端滑动到三珠接头上，直到停在止动鞘处为止。
9. 将推进器鞘沿着导管滑动，确保卡扣覆盖住动脉腔。这将减轻附着凸起和动脉接口通过组织时对皮下通道的拉扯。
10. 使用钝性推进器轻轻地将导管与推进器连接引入至出口部位，并从导管出口部位处造出一个皮下通道，在静脉入口部位显露出来。
警示：造通道时应小心，以免损伤周围血管。避免通道穿过肌肉。
警示：切勿拉扯或拖拽导管管道。如遇到阻力，进一步钝性分离可能便于插入。不得强推导管以通过通道。
11. 在造好导管通道后，将推进器鞘滑出导管并从导管远端部分的顶端拉出，即可移除推进器。
警示：轻微扭转，以免损坏导管。
警示：为避免损坏导管顶端，应始终保持推进器笔直，切勿倾斜拉出。
警示：在手术前检查导管顶端有无损坏。
12. 移除管芯标签，并将管芯的鲁尔锁定螺母与蓝色的静脉鲁尔锁定接头接紧。
13. 将探针的远端末端连同导管穿过导丝的近端末端，直至导丝脱离静脉鲁尔锁定接头。
14. 保持导丝在静脉中的位置，将导管推进上腔静脉和右心房交汇处，以确保最佳的血流量。
注意事项：为减少导管扭结，可能需要握住贴近皮肤的导管小幅度推进。
15. 将探针和导丝从静脉腔中移除。
16. 将小段余留导管环（“弯曲导管”）轻轻压入静脉入口部位的皮下囊袋中。
警告：植入导管时应小心避免任何锋角或尖角，因为这可能会影响血液流动或堵塞导管管腔的开口。
注意事项：为使本产品发挥最佳性能，请勿将卡扣的任何部分插入静脉中。
17. 采用 X 线透视调整导管的插入深度及末端位置。
18. 将注射器同时与两个延长管连接，然后打开管夹。从双腔中抽吸血液，以确认放置是否正确，以及导管是否正常运作。用肝素化生理盐水（延长管管夹上标有预充量）冲洗各管腔。血液应被轻易吸入。
注意事项：若任一管腔在抽吸血液时过度受阻，则可能需要旋转或重新定位导管，以获得足够的血流量。
注意事项：为保持通畅，两个管腔都必须植入肝素锁。
注意事项：建议“静脉”腔朝向头侧（对着头部）。
19. 冲洗完毕后立即夹上延长管。
20. 移除注射器并更换为注射帽。
警示：为避免发生气栓，应确保延长管在未被使用时始终用管夹夹紧，并在每次使用前抽吸并冲洗导管。
21. 正确放置导管的卡扣及通道部分。
22. 使用 X 线透视确认末端位置得当。远端的“静脉”末端应位于上腔静脉和右心房的交汇处，或置入右心房，以获得最佳的血流量。
警告：如未能使用 X 线透视确认导管的放置，可能会导致严重创伤或致命并发症。

固定及包扎
1. 缝合静脉出口部位为小段余留的导管环（“弯曲导管”）造出的囊袋。
2. 如有必要，缝合导管出口部位。
3. 用缝线翼将导管缝合在皮肤上。
警告：切勿缝合导管的任何部位。如果已通过缝合固定导管，须确保导管未被闭塞或切断。对导管用力过猛或存在粗糙边缘，可导致导管被撕裂。
注意事项：整个植入过程中，导管须予以固定／缝合。
4. 对导管出口部位和符合标准机构规程的通道插入部位使用透明的部位包扎。
警告：请勿在延长管或导管管体附近使用尖锐的器械。
警告：请勿使用剪刀拆除包扎。
警告：酒精或含酒精的消毒液可用于清洁导管／皮肤部位；但应小心以避免长期或过度接触这些液体。
警告：丙酮及含 PEG 的油膏可导致该装置出现故障，因此不应与聚氨酯导管一同使用。
5. 在患者记录上记录导管长度及导管批号。在记录中注明丙酮及含 PEG 的油膏不得用于该装置。

部位护理
1. 清洗导管周围的皮肤。
警告：不建议在伤口部位使用油膏／乳膏。
2. 用封闭敷料覆盖出口部位，并将延长管、夹具及密封帽留置在外以便透析团队进行处理。
3. 伤口包扎物必须保持清洁和干燥。
警示：除非由医师指示，否则患者不得浸湿或浸泡包扎。
注意事项：如果包扎粘性因大量汗液浸湿或意外浸湿而减弱，必须由医护人员在无菌环境中包扎敷料。

取出导管
与所有有创手术一样，医师将评估患者的解剖学和生理学需要，以确定最合适的导管取出技术。白色植入式储留卡扣可促进组织向内生长，因此必须通过外科手术取出导管。
警告 — 只有熟悉合适的取出技术的医师方可尝试取出植入的慢性透析导管。
警示：在取出导管前，应始终查看机构规程、潜在并发症及其治疗、警告及注意事项。

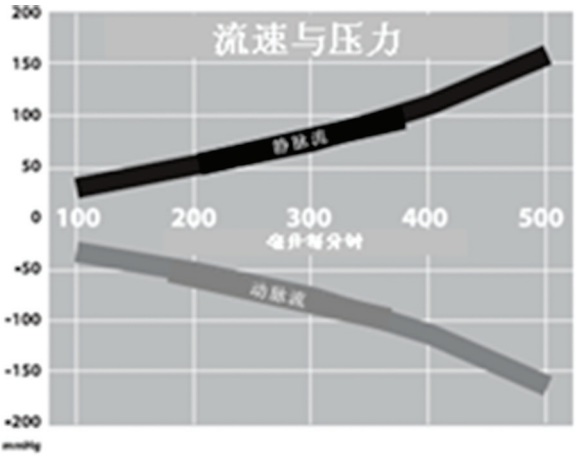
关于血液透析治疗的警示声明
- 血液透析应在医师的指示下采用获批准的机构规程执行。

- 治疗前，必须从各管腔清除肝素溶液，以避免患者全身肝素化。应基于机构规程进行抽吸。
- 透析开始前，应仔细检查与导管和体外回路的所有连接。
- 与该导管一并使用的附件与组件应包含鲁尔锁适配器。
- 应频繁执行目视检查，以检查是否有泄漏并尽可能减少失血或气栓。
- 如经常过分拧紧血液透析管路、注射器和密封帽，将缩短接头件使用寿命并可能导致其功能丧失。
- 在插入或使用的过程中，如导管或接阀出现泄漏，或接头脱离任何组件，则应夹紧导管，并采取所有必要措施和预防措施，防止失血或气栓。
- 为尽可能降低引发气栓的风险，导管在未与注射器、静脉输液管路或血路管连接时，应始终用管夹夹紧。
- 关闭延长管中心的所有管夹。经常夹紧鲁尔锁插接件附近或之上的管夹可能会使导管疲劳，使其可能断开连接。
- 经常在同一位置夹紧导管可能使导管变脆弱。对延长管用力过猛地拉拽或与粗糙物接触，可能导致延长管被切断或撕裂。

透析后肝素化
关于肝素浓度，请遵循机构规程。如导管并不立即用于治疗，则遵循建议的保持导管通畅指南。
1. 根据动脉和静脉延长管管夹所标的容量，将肝素／盐溶液注入两个注射器中。确保注射器不含空气。
2. 连接含有肝素溶液的注射器。
3. 打开延长管管夹。
4. 抽吸以确保不会有空气被送入患者体内。
5. 使用快速团注技术，将肝素溶液注入各个管腔。
   注意事项：为了保持治疗之间的通畅性，导管的各个管腔都必须植入肝素锁。
6. 关闭延长管管夹。
   注意事项：只应在抽吸、冲洗及透析治疗时打开延长管管夹。
7. 取出注射器。
   注意事项：在多数情况下，无需进行 48-72 小时的进一步肝素冲洗，但前提是管腔尚未被抽吸或冲洗。
8. 确保鲁尔盖有密封帽。

导管使用预充量
- 各个延长管管夹上标有动脉腔和静脉腔的预充量。

流速
- ProGuide 14.5 FR X 28 cm（顶端到接阀）导管（带有侧孔）的典型流速与压力比较



排除流量不足故障
流量不足的处理由医师酌情决定。疏通闭塞的管腔时，切勿过度用力。血液流量不足可能由凝块或血纤维蛋白外鞘引起的管腔闭塞所致，或由动脉孔接触静脉壁所致。如控制导管或变换动脉和静脉血液回路管没有帮助，医师可尝试使用血栓溶解剂溶解凝块。

单向堵塞处理
当管腔应能轻松冲洗，却无法抽吸血液时，就会出现单向堵塞。这种情况通常是由顶端错位造成的。以下其中一种调整方式可解决堵塞问题：
- 改变导管位置
- 改变患者体位
- 嘱示患者咳嗽
- 倘若无任何阻力，用无菌生理盐水强力冲洗导管，以使导管顶端移离血管壁。

感染
导管相关的感染是留置导管的严重问题。取出导管时，请遵循机构规程。

储存条件
切勿储存在高温或高湿处

运输条件
运输过程中应不暴露在高温或高湿下

留置时间：
大于30天，医生凭临床经验根据临床表征在需要时取出。

环氧乙烷灭菌
有效期:3 年

生产日期和失效日期：见产品标签
产品名称：血液透析用导管及附件
注册证编号： 国械注进20163104878
产品技术要求编号： 国械注进20163104878
型号、规格：见附页
注册人及生产企业名称：美国麦瑞通医疗设备有限公司 Merit Medical Systems, Inc
注册人及生产企业住所：1600 West Merit Parkway,South Jordan,Utah 84095
生产地址：1600 West Merit Parkway,South Jordan,Utah 84095
注册人及生产企业联系方式：1-801-253-1600
中国境内代理人及售后服务单位名称：麦瑞通医疗器械（北京）有限公司
中国境内代理人及售后服务单位住所：北京市朝阳区东大桥路9号楼2单元801室内B01、B02及B03单元
中国境内代理人及售后服务单位电话：010-85610788
中国境内代理人及售后服务单位传真：010-85616981

型号、规格：

PROGUIDE™血液透析用导管
63124，63128，63132，63136，63140，64124，64128，64132，64136，64140

PROGUIDE™血液透析用导管-基础套装
61124，61128，61132，61136，61140，62124，62128，62132，62136，62140

PROGUIDE™血液透析用导管-完整套装
DC21452419，DC21452823，DC21453227，DC21453631，DC21454035，DC21455550，DC01452419，DC01452823，DC01453227，DC01453631，DC01454035，DC01455550，DC21452419-NE5，
DC21452823-NE5，DC21453227-NE5，DC01452419-NE5，DC01452823-NE5，DC01453227-NE5

PROGUIDE™附件
DCVP1600，DCVP1500，DCVP1400

说明书编制或修订日期：2024年03月

结构及组成：产品由长期血液透析导管、导丝针芯、注射帽、扩张器、隧道器、穿刺针、导丝、导管鞘、安全手术刀、胶辅料、MAK套装(导管鞘、穿刺针、导丝)组成。环氧乙烷灭菌,一次性使用产品。